JUL 3 0 2002

K022029

Section II

510(K) Summary

Company Information:

Epimed International, Inc.
PO Box 1128
Gloversville, NY 12078
(518) 725-0209
Contact: Christopher B. Lake
Manager of RA/QA

Date Prepared:

June 18, 2002

Trade Name:

Spinal Needle

Common Name:

Spinal Needle

Product Class/Classification:

Class II

Predicate Device(s):

Manan Medical Products Spinal Needle (K852427)

Description:

The Spinal Needle consists of a stainless steel cannula with a ground beveled distal tip. A plastic hub is molded onto the proximal end of the cannula. A stylet is also provided with the device which consists of a stainless steel wire shaft and a molded plastic hub.

The Spinal Needle will be provided as a sterile, single use, disposable device. The Spinal Needle will be available in a variety of lengths and gauges.

Intended Use:

For the spinal administration of anesthetic agents to provide regional anesthesia.

Comparison to Predicate:

The Spinal Needle has identical physical and technical characteristics to the Manan Medical Products Spinal Needle marketed under K852427.

Non-Clinical Data:

Due to the fact that this product is purchased by Epimed from Manan Medical and is identical to the predicate device, bench testing to compare performance characteristics was not conducted.

Conclusion:

The comparison to the predicate device demonstrates that the Spinal Needle is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

Epimed International, Inc.

Christopher B. Lake
Manager of Regulatory Affairs/Quality Assurance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2002

Mr. Christopher B. Lake
Manager of Regulatory Affairs & Quality Assurance
Epimed International, Incorporated
141 Sal Landrio Drive
Crossroads Business Park
Johnstown, New York 12095

Re: K022029
Trade/Device Name: Quincke Spinal Needle
Regulation Number: 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: June 19, 2002
Received: June 21, 2002

Dear Mr. Lake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~K022209~~ K022029

Device Name: Spinal Needle

Indications For Use:

For the spinal administration of anesthetic agents to provide regional anesthesia.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022029